IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	Civil No. 03-353 (JFM)
	)	
v.	)	
	)	
SCT CORPORATION, d/b/a JEPPI NUT COMPANY, a corporation, and THEODORE PAVLOS and MARINA LILLIE, individuals,	)	CONSENT DECREE OF PERMANENT INJUNCTION
	)	
Defendants.	)	

Plaintiff, United States of America, having commenced this action by filing its Complaint for Injunction on the 5th day of February 2003, and Defendants SCT Corporation, doing business as Jeppi Nut Company, a Maryland corporation, and Theodore Pavlos, President of SCT Corporation, and Marina Lillie, Secretary/ Treasurer of SCT Corporation, individuals (herein collectively "Defendants"), and Defendants, without admitting or denying the allegations in the Complaint and having appeared and consented to the entry of this Decree, and the United States of America, having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over the subject matter and over all parties to this action.

2. The Complaint for Injunction states a claim for relief against Defendants under the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. §§ 301-397.

3. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce articles of food, as defined by 21 U.S.C. § 321(f), that are adulterated within the meaning of 21 U.S.C. §§ 342(a)(3) and (a)(4). The Complaint further alleges that Defendants also violate 21 U.S.C. § 331(k) by causing the adulteration of articles of food within the meaning of 21 U.S.C. §§ 342(a)(3) and (a)(4), while such articles are held for sale after shipment in interstate commerce.

The Old Facilities

4. Upon entry of this Decree, Defendants and each and all of their officers, directors, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of the contents of this injunction by personal service or otherwise, are hereby permanently restrained and enjoined, pursuant to 21 U.S.C. § 332(a) and the inherent authority of this Court, from all food operations, including receiving, processing, preparing, packing, packaging, roasting, manufacturing, holding, and distributing at or from their plants

at 312 N. High Street and 808 Low Street, Baltimore, Maryland, and from the facility located at 418 N. Colvin Street, Baltimore, Maryland (herein "the old facilities"). Nothing in this Decree shall prohibit Defendants from storing the food inventory presently held at the old facilities until such time as it is reconditioned or destroyed pursuant to the provisions of this Decree.

The Timonium Facility

5. Upon entry of this Decree, Defendants and each and all of their officers, directors, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of the contents of this injunction by personal service or otherwise, are hereby permanently restrained and enjoined, pursuant to 21 U.S.C. § 332(a) and the inherent authority of this Court, from receiving, holding, repacking (*i.e.*, receiving food in sealed packages, and without compromising the internal sealed packages, repacking the food into other containers), and distributing any article of food at or from 9 West Aylesbury Road, Timonium, Maryland (herein "the Timonium facility") unless and until:

A. Defendants establish and implement a written sanitation standard operating procedure ("SSOP") acceptable to

the United States Food and Drug Administration ("FDA"), as evidenced by written approval from FDA, that establishes adequate methods, facilities, and controls for receiving and holding articles of food to ensure that foods are not held under insanitary conditions whereby they may become contaminated with filth. Such methods, facilities, and controls shall include, but shall not be limited to, the following:

1) Ensuring that all floors, walls, ceilings, doors, and windows are properly maintained to prevent the entry of pests into the Timonium facility;

2) Taking all necessary steps to render the Timonium facility and all equipment therein suitable for use in receiving and holding articles of food to prevent the adulteration of the articles of food, and instituting procedures to ensure that the plant and equipment therein are continuously maintained in a sanitary condition;

3) Establishing a written sanitation control program for the Timonium facility and all food handling equipment contained therein to ensure that the plant and all equipment are continuously maintained in a sanitary condition so as to prevent the adulteration of food;

4) Assigning continuing responsibility for the operation of the sanitation control program to a person who, by

reason of background, experience, or education in sanitation work, is competent to maintain the Timonium facility in a sanitary condition and providing such person with the authority to achieve the necessary corrections; and

5) Establishing and documenting an employee training program that includes, at a minimum, sanitary food handling techniques.

B. Defendants shall select a person who, by reason of background, training and experience, is qualified to inspect food storage and distribution facilities. Said person shall inspect the Timonium facility, equipment, and all foods stored and distributed therefrom to determine whether an adequate sanitation control program has been established and whether the methods, facilities, and controls used for receiving, holding, and distributing articles of food have been implemented and are adequate to ensure the proper handling of food. After such person has thoroughly inspected Defendants' Timonium facility, he or she shall certify in writing to FDA whether the conditions set forth in Paragraphs 5(A)(1) through (5) have been met;

C. Defendants report to FDA in writing the actions they have taken to ensure that the articles of food that will be received, held at, repacked, and distributed from the Timonium facility will not be adulterated;

D. FDA notifies Defendants that Defendants appear to be in compliance with the requirements set forth in Paragraphs 5(A) through (C). As of the date of execution of this Consent Decree, FDA and Defendants agree that Defendants have provided to FDA documentation relating to the steps Defendants have taken to comply with Paragraphs 5(A) through (C). Execution of this Consent Decree by the United States shall serve as the notice to Defendants pursuant to this Paragraph 5(D) that FDA has reviewed the documentation supplied by Defendants and that FDA has determined that Defendants appear to be in compliance with the requirements set forth in Paragraphs 5(A) through (C) for receiving, holding, repacking, and distributing articles of food.

6. Upon entry of this Decree, Defendants and each and all of their officers, directors, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of the contents of this injunction by personal service or otherwise, are hereby permanently restrained and enjoined, pursuant to 21 U.S.C. § 332(a) and the inherent authority of this Court, from processing, preparing, roasting, packaging, and manufacturing (collectively "manufacturing"), and distributing any article of food manufactured at the Timonium facility, unless and until:

A. Defendants satisfy the requirements of Paragraphs 5(A) through (C), and apply the requirements of said Paragraphs with respect to all food operations, including receiving, packing, manufacturing, holding, and distributing any article of food at the Timonium facility;

B. Defendants have paid FDA for all foregoing costs. FDA will provide a bill for all foregoing costs to Defendants promptly after the close of the inspection; and

C. FDA inspects and notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in Paragraphs 5(A) through (C) and 6(A), the Act, and all other applicable laws. This notice is separate and in addition to any notice provided pursuant to Paragraph 5(D). FDA will provide notice to Defendants whether Defendants appear to be in compliance, or are not in compliance, with reasonable promptness after completion of the inspection under this paragraph.

7. Defendants shall bring any food, equipment, paper goods, and packing materials presently stored at the old facilities (herein "old articles") into compliance with the law prior to moving any such old articles into the Timonium facility. Defendants shall not commence attempting to bring the old articles into compliance with the law until Defendants have

submitted to FDA a written statement detailing the proposed reconditioning and have received written authorization to commence with reconditioning from FDA. Defendants' attempts at reconditioning will be witnessed by a duly authorized FDA representative. All old articles that are not successfully reconditioned pursuant to this paragraph shall be destroyed at Defendants' expense under the supervision of FDA. No articles of food shall be distributed without FDA prior written approval.

8. Defendants and each and all of their officers, directors, agents (including, but not limited to, contractors engaged in the processing, storage, and distribution of food for Defendants), representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing the following:

A. Introducing into interstate commerce, or delivering for introduction into interstate commerce any article of food, as defined by 21 U.S.C. § 321(f), that is adulterated within the meaning of 21 U.S.C. §§ 342(a)(3) or (a)(4); and

B. Receiving, packing, manufacturing, holding, or distributing any article of food in a manner that results in its being adulterated within the meaning of 21 U.S.C. §§ 342(a)(3) or (a)(4).

9. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses that FDA deems necessary to evaluate Defendants' compliance with this Decree. The costs of such inspections shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $67.17 per hour and fraction thereof per representative for inspection work; $80.49 per hour or fraction thereof per representative for analytical or review work; $0.36 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

10. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' places of business, and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted access to buildings, equipment, in-process and finished articles of food, containers, and packing material therein; to take photographs; to take samples of Defendants' finished and unfinished articles of food, containers, and packaging material; and to examine and copy all records relating to the receipt, packing, manufacturing, holding, and distribution of any and all articles of food. The inspections shall be permitted upon presenting a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

11. Defendants shall immediately cease receiving, packing, manufacturing, holding, or distributing any food, if, based on the results of any inspection, analysis of a sample or samples, or other information, FDA notifies Defendants that any article of food held in Defendants' plant(s) is adulterated, that there appear to be insanitary conditions in the plant(s), or that Defendants are not in compliance with the terms of this Decree or

the Act. In addition, Defendants shall, as and when FDA deems necessary, recall all articles of food that have been distributed or are under the custody and control of Defendants' agents, distributors, customers, or consumers. All costs of such recall(s) shall be borne by Defendants. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

12. Any cessation of operations, as described in Paragraph 11 above, shall continue until Defendants have received written notification from FDA that Defendants appear to be in compliance with the Decree and the Act, and such notice to be provided with reasonable promptness after receipt of information establishing compliance with the Decree and the Act. After a cessation of operations, and while determining whether Defendants are in compliance with the requirements of this Decree and the Act, FDA may require the Defendants to re-implement and re-institute any of the requirements of this Decree and take any other measures FDA deems necessary to prevent the adulteration of foods held and distributed by Defendants.

13. Defendants shall provide a copy of this Decree, personally or, if necessary, by registered mail, within ten (10) calendar days from the date of entry of the Decree by the Court, to each of their officers, directors, agents, representatives,

employees, successors, assigns, attorneys, and to any and all persons in active concert or participation with any of them. Defendants shall provide to FDA an affidavit of compliance within thirty (30) calendar days after the date of the entry of this Decree stating the fact and manner of compliance with this paragraph and identifying the names and positions of all persons who were so notified.

14. Defendants shall post a copy of this Decree on a bulletin board in the employee common area at Defendants' plants within ten (10) calendar days of the entry of this Decree, and shall ensure that the Decree remains posted for a period of six (6) months from the date of posting.

15. Within ten (10) days of entry of this Decree, Defendants shall hold a general meeting or series of smaller meetings for their employees, at which they shall describe the terms and obligations of this Decree.

16. Defendants shall notify FDA at least fifteen (15) calendar days before any change in location, ownership or character of their business, such as reorganization, dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporate structure of SCT Corporation, or the sale or assignment of any business assets that may affect

compliance with this Decree, including the sale of buildings or equipment used in connection with Defendants' food operations. Defendants shall provide a copy of this Decree to any successor or assign no later than fifteen (15) calendar days prior to the assignment or change in ownership. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

17. Defendants shall address all communications with FDA required under this Decree to Director, Baltimore District Office, Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215, and shall reference this civil action by case name and civil action number in such communications.

18. All decisions specified in this Decree shall be vested in the discretion of FDA, which discretion shall be reviewed, if necessary, by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be conducted without any discovery by either party and shall be based exclusively upon the written record that was before FDA at the time of the decision.

19. The Defendants shall reimburse FDA for FDA's costs of $16,165.05 for investigational expenses incurred due to the inspection that took place between April 23 and May 9, 2002 at Defendants' 312 N. High Street facility, and for such other and further relief as the Court may deem just and proper.

20. If any Defendant violates this Decree and is found in civil or criminal contempt thereof, Defendants shall, in addition to other remedies, reimburse plaintiff for its attorney fees, investigational expenses, expert witness expenses, and court costs relating to such contempt proceedings.

21. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED:

Dated this ____ day of _____, 2003.

_____
UNITED STATES DISTRICT JUDGE

We hereby consent to the entry of this Decree.

For Defendants:

SCT CORPORATION

For Plaintiff:

ROBERT D. MCCALLUM, JR.
Assistant Attorney General

/s/
MEREDITH MANNING
Hogan & Hartson L.L.P.
555 Thirteenth Street, N.W.
Washington, D.C. 20004
Tel: (202) 637-6585
Fax: (202) 637-5910
Attorney for SCT Corporation

/s/
THEODORE PAVLOS
President
SCT Corporation

/s/
FRANCIS R. LAWS
Thomas & Libowitz, P.A.
100 Light St., Suite 1100
Baltimore, MD 21202
Tel: (410) 752-4268
Fax: (410) 752-0979
Attorney for Theodore Pavlos

/s/
MARINA LILLIE
Secretary/Treasurer
SCT Corporation

/s/
FRANCIS R. LAWS
Attorney for Marina Lillie

THOMAS M. DIBIAGIO
United States Attorney

/s/
ARIANA WRIGHT ARNOLD
Assistant U.S. Attorney
Federal Bar No. 23000
6625 U.S. Courthouse
101 W. Lombard St.
Baltimore, MD 21201
Tel: (410) 209-4800
Fax: (410) 962-2310

/s/
SONDRA L. MILLS
Trial Attorney
Office of Consumer Litigation
Department of Justice
P.O. Box 386
1331 Pennsylvania Ave., N.W.
Washington, D.C. 20004
Tel: (202) 616-2375
Fax: (202) 514-8742

OF COUNSEL:

ALEX AZAR II
General Counsel
Department of Health and
Human Services

DANIEL E. TROY
Chief Counsel
Food and Drug Administration

MICHAEL N. VARRONE
Trial Attorney
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857